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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,902	01/11/2001	Roberts S. David	PC9047D	1327

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EXAMINER	
SHAHNAN SHAH, KHATOL S	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 01/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/758,902	DAVID ET AL.	
	Examiner	Art Unit	
	Khatol S Shahnan-Shah	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/22/2003 has been entered.

2. Applicants' amendment and response received October 14, 2003 is acknowledged. The amendment has been entered. Claim 18 has been amended.

3. Currently claims 18-19 are pending and under consideration.

Prior Citations of Title 35 Sections

4. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior office action.

Prior Citations of References

5. The references cited or used as prior art in support of one or more rejections in the instant office action have been previously cited and made of record. No form PTO-892 or 1449 have been submitted with this office action.

Rejections Maintained

6. Rejection of claims 18-19 under 35 U.S.C. 103, made in paragraph 5 of the office action mailed 12/14/2001, paper # 4 is maintained.

The rejection was as following:

Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al. (The veterinary record, May 2, 1987) and Geresi et al. (Ann. Immuno. Hung Vol. 25, pp. 37-40 1985) in view of Wu et al. (The Journal of Immunology, Vol. 148, pp. 1519-1525, 1992) and Gluck et al. (US Patent 5,879,685).

Claims are drawn to a multicomponent clostridial vaccine composition comprising a viral antigen and a saponin adjuvant.

Green et al. teach the formulation of a multivalent clostridial vaccine in analogous art (see page 435) for the purpose of stimulating a protective immune response against multiple strains and species of this pathogen. Green et al. teach multicomponent clostridial vaccines such as Covexin 8, Hepatavac and Tasvax (see table 1). Green et al. teach the inclusion of six or more clostridial immunogens such as toxoids from *Cl. chauvoei, Cl. septicum, Cl. tetani, Cl. nvoyi, Cl. haemalyticum and Cl. perfringins* (type B, C and D) for the realized reduced threat of loss of livestock, wherein the use of six or more of clostridial immunogens would have provided for a broader range of immune response against clostridial pathogens and increase the likelihood of protection against infection by a broader range of species or strains of clostridium. Green et al. teach aluminum hydroxide as the adjuvant (page 438, column 1). Green et al. do not teach viral antigen.

Geresi et al. teach the formulation of multivalent clostridial vaccine compositions, which also comprise a viral immunogen (see page 38). The reference differs from the instantly claimed invention by failing to show the use of saponin as an adjuvant.

Wu et al. show the use of saponin adjuvant in association with an antigen, wherein the exemplified vaccine comprised a viral antigen (see abstract and results in page 1521 and

discussion in page 1523). Wu et al. teach that vaccine formulations containing the saponin adjuvant produced significantly higher titers of antibody than alum absorbed vaccines. Wu et al. do not teach a respiratory virus.

Gluck et al. teach an immunostimulating combination of influenza virus and *Clostridium tetani* (see abstract and claims 6-9).

Therefore, it would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to modify or combine the compositions of Green et al. and Geresi et al., include a respiratory virus taught by Gluck et al. and to include the saponin adjuvant of Wu et al. because all of the references are directed to the formulation of vaccines for the attainment of enhance immune response. One with ordinary skill in art would have been motivated to combine these compositions because Green et al and Geresi et al. both teach the formulation of multicomponent clostridial vaccines, Gluck et al. and Geresi et al. teach the inclusion of viral antigens in bacterial vaccine composition and Wu et al. teach the use of saponin as an adjuvant which provides for an enhanced immune response when in association with either a clostridial antigen or a viral antigen, respectively. In the absence of unexpected results, Green et al. and Geresi et al., in view of Gluck et al. and Wu et al. obviate the instantly claimed invention.

Applicants' arguments filed 10/14/2003 have been fully considered but they are not persuasive.

Applicants argue that cited art does not provide any suggestion or motivation to make the claimed invention. Applicants further argue, " that a principle feature of the present invention

resides in the unique recognition that the water soluble adjuvant saponin can be used in place of a depot adjuvant, e.g aluminium compound"

In response to applicants' argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation of combining immunogenic compositions containing *Clostridium* species and respiratory virus is coming from teachings of Gluck et al. Gluck et al. teach an immunostimulating combination of influenza virus and *Clostridium tetani* (see abstract and claims 6-9). Use of different adjuvants such as saponin is well known in the art of vaccine preparation and saponin adjuvant has been commercially available (i.e Quil A) (see Wu et al. page 1519 right column). Therefore one of ordinary skill in the art would have been motivated to replace the aluminum hydroxide adjuvant of Green et al. with the saponin adjuvant.

New Rejections

7. Claim18 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The added material, which is not supported by the original disclosure, is as follows:

Amended claim 18 now recites the limitation " wherein said vaccine composition does not contain an aluminium compound - based depot adjuvant". This new limitation is not supported by the original disclosure.

Applicant is required to cancel the new matter in the reply to this Office Action.

Conclusion

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached from 7:30 AM - 4 PM on Monday through Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

Art Unit 1645

January 10, 2004

RODNEY P SWARTZ, PH.
PRIMARY EXAMINER